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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/057,108

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Geert Plaetinck

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EXAMINER

SHIN, DANA H

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/057,108	Applicant(s) PLAETINCK ET AL.	
	Examiner DANA SHIN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13,17-22,25-27 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13,17-22,25-27 and 54-56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-22-2009</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

This Office action is in response to the communications filed on December 22, 2009.

Currently, claims 13, 17-22, 25-27, and 54-56 are pending and under examination on the merits in the instant case.

The following rejections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Terminal Disclaimer

The terminal disclaimer filed on December 22, 2009 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 7,005,423 B1 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments and Amendments

Withdrawn Rejections

Any rejections not repeated in this Office action are hereby withdrawn.

Maintained Rejections

Claim Rejections - 35 USC § 103

Claims 13, 17-22, 25-27, and 54-56 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Timmons et al., Raftery et al., Wang et al., Vanfleteren, and Talkad et al. for the reasons of record as set forth in the Office action mailed on June 22, 2009 and for the reasons stated below.

Applicant's arguments filed on December 22, 2009 have been fully considered but they are not persuasive. Applicant argues that the claims are not obvious because Timmons et al. do not teach whether dsRNA was successfully transcribed and expressed or other elements claimed in the instant case. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The instant obviousness rejection is based on a combination of five prior art references including the Timmons et al. reference. As such, there is no requirement that the Timmons et al. reference must disclose and teach all elements of the claims. First, it is indisputable that Timmons et al. taught, prior to the date of the invention, that one can feed bacteria expressing dsRNA to *C. elegans* for down-regulating a desired target expression, which is silenced by the dsRNA carried by the bacteria fed to *C. elegans*, wherein feeding bacteria has long been known as the methodology to grow or culture *C. elegans* as taught by Vanfleteren et al. Second, it is an undeniable fact that making and using an expression vector that successfully transcribes a dsRNA in bacteria such as *E. coli*, wherein the expression vector comprises two promoters adapted to transcribe a DNA sequence to produce a dsRNA, were technically feasible and known in the art as taught by Raftery et al. and

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Wang et al. Third, it was an art-recognized scientific fact that RNase III cleaves dsRNAs and that one can make *E. coli* strains that are deficient in dsRNA-cleaving RNase III as taught by Talkad et al., wherein such RNase III-deficient *E. coli* strain would have reasonably appeared as suitable or beneficial food source for *C. elegans* when and if a person of ordinary skill in the art is attempting to feed dsRNA-containing *E. coli* to *C. elegans*. See pages 6-8 of the last Office action mailed on June 22, 2009. It is noted that applicant's arguments are completely devoid of and silent about how or why the combination of the cited prior art references and the technology disclosed by the references are insufficient to render the claims *prima facie* obvious. That is, applicant's arguments merely amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the cited prior art references.

Applicant points out various case laws and court decisions such as *In re Rijckaert* (Fed. Cir. 1993), *Ex parte Levy* (Bd. Pat. App. & Inter. 1990), and *KSR Int'l Co. v. Teleflex Inc* (Supreme Court, 2007) and argues that Timmons et al. do not teach the claimed methods. Again, the teachings of Timmons et al. are not the only basis applied in the instant rejection, and applicant's mere quotations of courts' opinions do not show the patentable novelty which applicant thinks the claims present in view of the state of the art disclosed by the references cited in the instant rejection. Again, there is no clear rebuttal argument or articulation as to why the claims are not obvious in view of the combined teachings of the prior art references that are not limited to the Timmons et al. reference.

Applicant further argues that the nonobviousness of the claims is supported by the declaration filed on December 22, 2009. First, applicant's attention is directed to the fact that the

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declaratory statements contained in the declaration under 37 CFR 1.132 pertain to the ground of rejection based on Fire et al., Zdinak et al., Talkad et al., and Noren et al., which is not the ground of rejection applied herein. As explicitly stated in paragraph 2 of the declaration, the declaration submitted on December 22, 2009 pertains to the 103(a) rejection in the Office action dated October 27, 2008. Second, even if paragraph 17 of the declaration (specifically pointed out by applicant) were to pertain to the instant ground of rejection, the opinion of the declarant expressed in paragraph 17 does not show that there was no reasonable expectation of success in making and feeding an RNase III-deficient bacterium comprising a vector that is capable of producing a dsRNA, which down-regulates target expression in *C. elegans*. Note that for obviousness under §103, “all that is required is a reasonable expectation of success”, and it does not require “absolute predictability of success”. See *In re O'Farrell*, 853 F.2d 894, 7 USPQ2d 1673 (Fed. Cir. 1988) at 1681. Since the declaration is not based on the instant ground of rejection and thus does not address or analyze the teachings of the prior art references pertinent to the instant rejection, it is concluded that the opinions expressed in the declaration do not appropriately attack the obviousness established in the instant case.

In view of the foregoing, claims 13, 17-22, 25-27, and 54-56 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Timmons et al., Raftery et al., Wang et al., Vanfleteren, and Talkad et al.

Double Patenting

Claims 13, 17-22, 25-26, and 54 remain rejected on the ground of nonstatutory obviousness-type double patenting for the reasons of record as set forth in the Office action mailed on June 22, 2009 and for the reasons stated below.

Applicant's arguments filed on December 22, 2009 have been fully considered but they are not persuasive. Applicant argues that the claims are not obvious over claims 41-46 of 12/055,607 because there is no reason to omit inter-promoter region, cloning site, and terminators claimed in the copending application in order to obtain the claimed invention. It appears that applicant is confused about the claimed subject matter in the instant case. In no way are the present claims written to exclude or omit inter-promoter region, cloning site, and terminators claimed in the reference claims. That is, the expression vector claimed in the method claims in the instant application "comprises" the elements recited in the claims. As applicant must be aware, the transitional phrase "comprises" does not exclude unrecited elements. See MPEP 2111.03. As such, whether or not the instant claims are silent about the additional elements recited in the reference claims does not determine the patentability of the instant claims over the reference claims. In addition, examiner does not understand how applicant is able to argue that the instant claims do not read on a vector comprising cloning sites or a terminator sequence as it is inherent that a cloning vector (see Figure 4, Figure 8, Figures 13-14, Figures 17-18 of the instant application, for example) necessarily includes cloning sites and a terminator sequence. Since applicant's arguments are not persuasive, this rejection is maintained.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 22, 2009 is considered by the examiner except Citation No. C23, which is in non-English language.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun Sajjadi (Acting SPE) can be reached on 571-272-3311. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Dana Shin
Examiner
Art Unit 1635

/Dana Shin/
Examiner, Art Unit 1635